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REMARKS

Claims 1, 3-5, 7, 10-13, and 30-33 are pending in the application. Claims 2, 6, 8, 9, 14, 16, 17, 19, 21, 22, 27 and 29 have been withdrawn. Claims 18, 20, 23-26 and 28 are allowed, and claims 1, 3-5, 7, 10-13 and 30-33 are rejected. Claims 1 and 30 have been amended. Support for the amendment can be found throughout the specification and drawings. No new matter has been added. Reconsideration of the claims is respectfully requested.

Claims 1, 3-5, 7, 10-13, and 30-33 are rejected under 35 USC 102(b) as being anticipated by Krueger et al (5,578,076). Applicants respectfully traverse the rejections.

Claim 1 has been amended to clarify that the leaflet fastener comprises at least one pair of arms, at least one of the arms of the pair of the arms having a pointed member for fastening two adjacent tissue heart valve leaflets, wherein the arms pivot from one orientation to a gripping position with ends of respective paired arms being adjacent and directed toward each other. Pointed members for fastening two adjacent tissue heart valve leaflets are shown, for example, in Figures 13B, 14B, 15B and 15G.

Krueger does not disclose a heart valve fastener comprising at least one pair of arms, at least one of the arms of the pair of the arms having a pointed member for fastening two adjacent tissue heart valve leaflets and does not have arms that pivot from one orientation to a gripping position with ends of respective paired arms being adjacent and directed toward each other. Krueger shows hangers 16, 366 having arms 16, 374 with legs 74, 76, or a tab 376, respectively, which is used for attachment of hanger 16, 366 to valve holder 14, 300. Holder 14, 300 is attached to mechanical heart valve 12, 202. Hanger 16, 366 is used to suspend the holder with attached valve in packaging for shipment and storage (col. 3, lines 37-39 and col. 6, lines 35-37). Tab 376 is shown in cross section in Figure 18, and has a thickness for insertion into holder, with a rounded end. There is no reason to make the end of Krueger's tabs 376 pointed since tabs 376 do not need to pierce tissue. Obviously, tabs 376 are not pointed members for fastening two adjacent tissue heart valve leaflets as presently claimed, and are not adjacent each other.

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Legs 74,76 have squared off ends and also are not adjacent each.

Applicants respectfully disagree with the Examiner that the arms of Krueger would have been capable of performing the use as claimed. Hanger 14, 366 is simply to hold the holder and valve in an upright position in the packaging. The Examiner has provided no objective evidence that the pair of arms 16, 374 with curved segments 74, 76 or tabs 376 are capable of fastening adjacent tissue valve leaflets. Only a conclusory statement related to the claim language is provided. Applicants respectfully request the Examiner provide documentary evidence. MPEP 2144.03.

In addition, the hanger in Krueger is not used within the heart. The hanger is removed from holder/valve when the assembly is removed from the packaging and the holder is used to implant the mechanical heart valve (col. 4, lines 6-7). The hanger 366 is not even used during the implant of the heart valve. It is clear that tabs 376 or legs 74,76 cannot come close enough to grasp leaflets within the heart, and are not adjacent each other. The tabs or legs of Krueger remain spaced apart a considerable distance to accommodate a large mechanical heart valve. Thus, Krueger does not teach every element of claim 1 and withdrawal of the rejection to claim 1, and claims dependent on claim 1, is requested.

Claim 30 has been amended to clarify that the cap is slidable relative to the gripper. Release points 370, what the Examiner terms the cap in Krueger, is not slidable. Thus, Krueger does not teach every element of claim 30 and withdrawal of the rejection to claim 30, and claims dependent on claim 30, is requested.

Applicants respectfully request withdrawal of the rejection of claims 1, 3-5, 7, 10-13 and 30-33 under 35 U.S.C. §102 (b) as being anticipated by Krueger, et al.

In view of the reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at

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(612) 334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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